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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,368	06/08/2006	Maurice Loretto	1131-16-PCT-PA-TD	6260
22145 7590 01/27/2009 KLEIN, O'NEILL & SINGH, LLP 43 CORPORATE PARK SUITE 204 IRVINE, CA 92606				
EXAMINER				
AHMED, SHEEBA				
ART UNIT		PAPER NUMBER		
1794				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/562,368

Applicant(s)

LORETTI ET AL.

Examiner

SHEEBA AHMED

Art Unit

1794

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SG/US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendments

1. Amendments to claims 1, 3, 5-7, 9-14, and 16 have been entered in the above-identified application. New claims 17-24 have been added. **Claims 1-24 are pending.**

Claims 20-24 are directed to a nominal method. The Examiner would like to remind the Applicants that if substantial amendments are made to the method claims such that they no longer recite a nominal method then the method claims will be restricted as being directed to an invention that is independent or distinct from the invention originally claimed. Since applicants have received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 5, 8, 11, 14-16, 18, and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recites "an intermediate layer comprising or substantially consisting of ethylene/vinyl alcohol copolymer, having a defined ethylene content of 27 to 38, in particular 29 to 32 mol-%". It is unclear what is meant by "comprising or substantially

consisting of". The transitional phrases "comprising", "consisting essentially of" and "consisting of" define the scope of a claim with respect to what unrecited additional components or steps, if any, are excluded from the scope of the claim and in this case it is unclear which transitional phrase is used to define the scope of the claim. Similar ambiguity in the transitional phrase is present in several claims, such as 8, 18, and 22.

Claim 8 recites that "said oxygen absorber contains or consists of Fe or Fe(II)-salts". Does the oxygen absorber consist of Fe salts or Fe(II) salt or does the oxygen absorber consist of iron or Fe(II) salts?

Claim 11 recites that "said oxygen absorber is contained in the respective layer/layers in an amount of 1 to 100 mg/g, particularly 5 to 20 mg/g related to the weight of the respective layer.

Claims 14-16 provides for the use of the multilayer film, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 18 recites that the "intermediate layer comprising or substantially consisting of ethylene/vinyl alcohol copolymer, having a defined ethylene content of 27 to 38, in particular 29 to 32 mol%. Similarly, claim 22 recites that "the intermediate layer comprises or substantially consists of ethylene/vinyl alcohol copolymer, having a defined ethylene content of 27 to 38, in particular 29 to 32 mol%".

Furthermore, regarding claim 5, 11, 18, and 22, the phrase "in particular" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention.

Appropriate corrections or clarification is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 14-16 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-5, 13, 17, 19, 20, 22, and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Loretti (EP 0965443 A1).

Loretti discloses a sterilizable coextruded polymer composite tubular film, the use of such tubular films for the preparation of containers intended for medicaments or infusion solutions. The sterilizable coextruded polymer composite tubular film for use as containers for solutions, suspensions, solids or mixtures for parenteral or enteral nutrition or tube feeding, optionally in a spatially separated arrangement of the contents has a three-layered structure of the tubular film with the following layer sequence : a) polyamide 11 and/or polyetherblock amide b) ethylene/vinyl alcohol copolymer with an ethylene content of 27 to 38 mole %; and c) homophase polypropylene copolymer which is suitable for forming the interior surface of the container. The three-layered structure can be used to prepare tubular films and, therefrom, sterilizable containers, especially bags, by a multilayer coextrusion blowing method which enable an ecologically compatible disposal. The core of the three-layered structure of the blown film according to the invention is the ethylene/vinyl alcohol copolymer layer with an ethylene content of 27 to 38 mol %. The ethylene/vinyl alcohol copolymer layer b) should have a thickness of 5 to 35 microns. The outer layer a) should have a thickness of 40 to 100 microns and the homophase polypropylene copolymer layer c) which is suitable for forming the interior surface of the said container and thus, being in direct contact with the content, should preferably have a thickness of 60 to 100 microns (See Paragraphs 0001 to 0024). With regard to the limitation that the sterilizable multilayer film has an oxygen transmission rate at 23 °C through the multilayer film determined by

the oxygen transmission of the intermediate layer is less than 0.7 ml/m²d and that the outer layer allows desorption of water absorbed in the intermediate layer during sterilization after said sterilization at 121 °C, the Examiner takes the position that such property limitations are inherent in the multilayer structure taught by Loretti given that the structure of the multilayer film (i.e., the number of layers, etc.) and the chemical composition of each layer within the multilayer film is identical to that of the claimed multilayer film. All limitations of claims 1-5, 17, 19, 20, 22, and 23 are either disclosed or inherent in the above reference.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 6, 18, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Loretti (EP 0965443 A1) in view of Hogstrom et al. (US 5741566 A).

Loretti, as discussed above, does not teach that the outer layer may be a polyethylene terephthalate layer. However, Hogstrom et al. disclose an autoclavable multi-layer film formed of thermoplastic materials capable of being processed into hollow shapes and useful for packaging oxygen sensitive materials. The film includes sequential layers A--B--C--D--C--B'--A', wherein the A and A' are layers substantially water and water vapor resistant, wherein at least one of the layers A and A' is made of

polyolefins, polyethylene terephthalates, or co-polymers of polyethylene terephthalates (See Abstract). The outermost layers A and A' front the environment and shall be made from a moisture resistant material capable of withstanding both water vapor and liquid water. These layers can be made from the same or different polyolefines or PET (polyethylene-terephthalate) or copolymers of PET (Column 2, lines 55-67).

Accordingly, it would have been obvious to one having ordinary skill in the art to use a polyethylene terephthalate outer layer in the multilayer film taught by Loretti given that Hogstrom et al. teach that the outermost layer fronts the environment and shall be made from a moisture resistant material capable of withstanding both water vapor and liquid water and that such layers can be made from PET (polyethylene-terephthalate) or copolymers of PET.

6. Claims 7-12 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Loretti (EP 0965443 A1) in view of McKedy (US 5,262,375 A).

Loretti, as discussed above, does not teach that the laminate or any of the layers within the laminate contain an oxygen absorber such as iron salts.

However, McKedy discloses an oxygen-absorbing composition containing particulate annealed electrolytically reduced iron of between about 100 mesh and 325 mesh in a packet for absorbing oxygen including a stain and grease resistant envelope containing the oxygen-absorbing composition (See Abstract). Particulate iron is known as an oxygen absorber because it readily combines with oxygen (Column 1, lines 8-10). The oxygen absorber is intended to be used with all types of food products which

may be deleteriously affected by the presence of oxygen or any other type of product which is packaged and which must be protected from the deleterious affect of oxygen (Column 4, lines 61-68).

Accordingly, it would have been obvious to one having ordinary skill in the art to add an oxygen absorber to any of the layers of the multilayer film taught by Loretta given that McKedy et al. teach that particulate iron is known as an oxygen absorber because it readily combines with oxygen. Furthermore, it would have been obvious to one having ordinary skill in the art to optimize the amount of the oxygen absorber in the multilayer laminate given that the larger the amount of the oxygen absorber present, the greater the amount of oxygen absorbed by the laminate.

Response to Arguments

7. Applicant's arguments filed November 4, 2008 have been fully considered but they are not persuasive. Applicants traverse the rejection under 35 U.S.C. 102(b) as being anticipated by Loretta (EP 0965443 A1) and submit that even though the lower limit of the outer layer overlaps with the upper limit of the claimed outer layer, this overlap does not constitute anticipation, given that the cited reference discloses preferred ranges. First, the Examiner would like to point out that when the prior art discloses a range which touches or overlaps the claimed range, in order to anticipate the claims, the claimed subject matter must be disclosed in the reference with "sufficient specificity to constitute an anticipation under the statute." In this case, the overlapping range is taught with "sufficient specificity" given that the reference states that the outer

layer should have a thickness of 40 to 100 microns. Second, under 35 U.S.C. 102, the entire disclosure of a prior art reference and not just the preferred embodiments can be relied upon to reject the claims.

Applicants further traverse the Examiner's position that the oxygen transmission rate limitations are inherent in the multilayer structure taught by Loretti given that the structure of the multilayer film (i.e., the number of layers, etc.) and the chemical composition of each layer within the multilayer film is identical to that of the claimed multilayer film. Applicants state that the burden is on the Examiner to provide support why the claimed properties are inherent to the reference multilayer film. In response, the Examiner would like to point out that the inherency position has been taken given that the structure of the multilayer film (i.e., the number of layers, etc.) and the chemical composition of the multilayer film are identical. Furthermore, once a product appearing to be substantially identical is found and a 35 U.S.C. 102 rejection has been made, the burden shifts to the Applicants to show the unobvious difference.

Hence, the above rejection is maintained.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHEEBA AHMED whose telephone number is (571)272-1504. The examiner can normally be reached on Monday-Friday from 8am to 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rena Dye can be reached on (571)272-3186. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sheeba Ahmed/
Primary Examiner, Art Unit 1794